

as compared to circular TAV expanded to 23, 21, and 19mm, respectively. In addition, in the presence of 0.75 eccentricity, the maximum principal stress value in the commissures was increased by 173%, 213% and 149%, as compared to circular TAV expanded to 23, 21, and 19mm, respectively.

CONCLUSIONS Computational models were developed to study the synergistic impact of incomplete and eccentric TAV stent expansion on leaflet stress distributions. Eccentric and incomplete stent deployment induce localized high stress regions within the TAV leaflets. Increased mechanical stress on TAV leaflets may lead to accelerated tissue degeneration and diminished long-term valve durability.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Durability, Leaflet damage, Transcatheter aortic valve replacement

TCT-622

Is there a therapeutic limit to sequential aortic valve-in-valve? Hydrodynamic analysis of sequential valve-in-valve using the novel Inovare prosthesis in surgical aortic bioprosthesis

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BACKGROUND The sequential implantation of a transcatheter heart valve (THV) within a similar device, also known as valve-in-valve-in-valve, will be an important concept in the future, considering patients with elevated surgical risk and failed THVs within surgical aortic valves (SAV). However, this procedure has not been studied in depth, especially considering the reduction of effective orifice area (EOA) and the elevation of transvalvular gradients (ΔP). Our objective was to evaluate the hydrodynamic performance of valve-in-valve-in-valve, determining the therapeutic limits.

METHODS Using a pulse duplicator, three sets of valve-in-valve-in-valve were tested. FDA specifications for cardiac output, mean arterial pressure and heart rate variation were used. EOA and ΔP were measured. First set was a 23mm surgical valve with two sequential THV implants of 22mm and 20mm. Second set was a 25mm surgical valve with two sequential THV implants of 24mm and 22mm. The last set was a 25mm surgical valve with three sequential implants of 24mm, 22mm and 20mm.

RESULTS The results obtained from the three sets are represented on Table 1.

	EOA (cm ²)	ΔP (mmHg)
20mm THV within 22mm THV within 23mm SAV	0.97	12.8
22mm THV within 24mm THV within 25mm SAV	0.97	13.46
20mm THV within 22mm THV within 24mm THV within 25mm SAV	0.86	15.32

CONCLUSIONS The use of multiple THVs as an alternative to repeated conventional aortic valve replacement can be considered feasible after hydrodynamic testing. Satisfactory results can be obtained with up to 22mm THVs. When a 20mm THV was needed, results were borderline to prohibitive, depending on whether it was the 2nd or 3rd implantation. The less-than-optimal results might be due to device underexpansion.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Transapical, Transcatheter aortic valve replacement, Valve-in-valve

TCT-623

Transcatheter Aortic Valve Replacement In Women Versus Men: An Analysis of the CoreValve US Pivotal and Continued Access Trials

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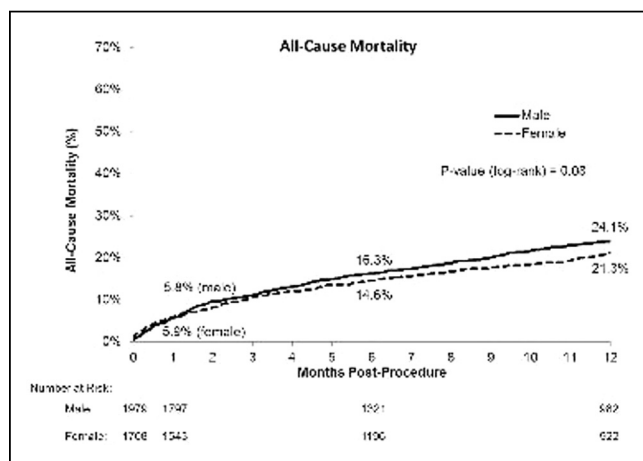
BACKGROUND There is limited data, especially from the US, on sex-related differences with regards to patient characteristics and outcomes with the CoreValve prosthesis. The objective of this study is to compare the baseline characteristics and clinical outcomes in women and men undergoing transcatheter aortic valve replacement with the CoreValve prosthesis in the United States.

METHODS Patients used for this analysis include all patients who underwent TAVR in any one of the 4 CoreValve US trials- the CoreValve Pivotal extreme and high risk trials as well as the CoreValve Continued Access extreme and high risk trials. Data from 3687 patients including 1708 women and 1979 men undergoing TAVR were included for analysis.

RESULTS Women comprised 46% of the final cohort and at baseline had a higher STS score (9.6% vs. 8.3%). While there was no difference in baseline NYHA classification, women tended to have fewer cardiac comorbidities and a lower rate of coronary artery disease including fewer MIs, CABGs, and PCIs. Women were also less likely to have peripheral vascular disease, a pre-existing pacemaker, or a prior stroke. Conversely, women had increased frailty indices as measured by KATZ ADL deficits, walk times, and grip strength. At baseline women had a higher mean gradient across the aortic valve (51.5 vs 44.3mmHg) and smaller EOA (0.66 vs. 0.79cm²). From a procedural standpoint, women were slightly more likely to require alternative access (21% vs 18.35%) and tended to receive smaller sized valves. The 30-day and 1-year outcomes are summarized in the table below.

CONCLUSIONS Women, who account for nearly half of the population undergoing TAVR within the CoreValve US trials, tend to have fewer cardiac comorbidities and increased frailty as compared to men. While differences exist in procedural risks between men and women undergoing TAVR with the CoreValve prosthesis, there was no difference in 30-day or 1-year mortality.

	30 -days			1 year		
	Male (N=1979)	Female (N=1708)	P-value	Male (N=1979)	Female (N=1708)	P-value
All-Cause Mortality, %	114 (5.8)	100 (5.9)	0.87	406 (24.1)	315 (21.3)	0.08
Cardiovascular, %	109 (5.6)	98 (5.8)	0.74	305 (18.1)	242 (16.4)	0.23
Stroke, %	79 (4.0)	95 (5.7)	0.02	129 (7.7)	141 (9.3)	0.05
Major, %	42 (2.1)	60 (3.6)	0.01	72 (4.5)	86 (5.6)	0.04
All-Cause Mortality or Major Stroke, %	142 (7.2)	140 (8.2)	0.22	434 (25.6)	353 (23.4)	0.32
Bleed, %	615 (31.2)	728 (42.7)	<0.0001	694 (36.7)	781 (46.8)	<0.0001
Life-Threatening/ disabling, %	200 (10.2)	244 (14.3)	0.0001	261 (14.3)	290 (17.9)	0.002
Major Vascular Complication, %	96 (4.9)	165 (9.7)	<0.0001	103 (5.3)	168 (9.9)	<0.0001
Acute Kidney Injury, %	222 (11.3)	175 (10.4)	0.38	222 (11.3)	175 (10.4)	0.38
Myocardial Infarction, %	16 (0.8)	18 (1.1)	0.43	33 (2.1)	34 (2.4)	0.52
Cardiac Tamponade, %	11 (0.6)	42 (2.5)	<0.0001	15 (0.8)	43 (2.5)	<0.0001
New Permanent Pacemaker Implant, %	453 (23.2)	311 (18.6)	0.0007	508 (27.0)	346 (21.4)	0.0001
KCCQ Overall Summary Score Change from Baseline	22.4 ± 27.4	22.4 ± 27.2	0.96	28.0 ± 28.1	28.9 ± 26.4	0.53



CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS CoreValve, TAVR, Women

TCT-624

Acute Renal Injury and Mortality After Transcatheter Aortic Valve Replacement

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BACKGROUND The presence of acute renal injury (AKI) enhances morbimortality after surgical aortic valve. However, the risk of periprocedural AKI and its association with outcomes after transcatheter aortic valve replacement (TAVR) is still incompletely understood. This prospective observational study aims to determine the incidence of AKI, its predictors and impact on 30-days and 1-year mortality.

METHODS We assessed data from 225 consecutive patients with severe symptomatic aortic stenosis submitted to TAVR between January 2009 and February 2015 on two tertiary cardiological centers, conducted by the same heart team. All patients used an ionic, low-osmolar, low-viscosity contrast. Kidney injury was defined according to VARC (Valve Academic Research Consortium) criteria, following AKIN system, and analyzing data until the seventh day post-procedure. Three patients were excluded due to death during the procedure, considering those deaths not related to renal dysfunction. One patient was excluded due to incomplete data. The remaining 221 patients comprised the population of the current analysis separated in two groups: AKI group (group 1) and non-AKI group (group 2). Follow-up was performed on 30 days and after one year.

RESULTS At baseline, mean age was 82.24 ± 6.78 years, 53% women, transfemoral access 75.6%. Fifty two patients (23.5%) developed AKI until seventh day of procedure. Groups 1 and 2 were similar, except for EuroSCORE II ($8.66\% \pm 5.64\%$ vs $7.34\% \pm 8.58\%$, $p = 0.02$) and glomerular filtration rate (GFR) ($39.59 \text{ ml/min.1.73m}^2 \pm 13.62$ vs. 48.49 ± 19.6 , $p = 0.002$). Overall 30 days-mortality and 1-year mortality was 6.3% and 14.0%, respectively. Both 30-day mortality (23.1% vs 1.2%, $p < 0.001$) and 1-year mortality (44.2% vs 4.7%, $p < 0.001$) were higher in group 1. In multivariable-adjusted models, the only independent predictor for AKI after TAVR was baseline GFR [hazard ratio (HR) 1.37, CI 95% 1.08-1.77, $p = 0.01$]. Regarding long term follow-up, AKI (HR 19.86, CI 95% 7.31-53.98, $p < 0.001$) and COPD (HR 3.14, CI 95% 1.05-9.40, $p = 0.04$) were independent risk factors for 1-year mortality, whilst hypertension (HR 0.269, 0.09-0.80, $p = 0.01$) was shown to be protective for long term mortality.

CONCLUSIONS In this TAVR sample, baseline GFR was the only independent predictor of AKI, and patients who developed it had significantly higher mortality at 30 days and 1 year. Acute renal impairment was the strongest risk factor for mortality and adverse cardiovascular events that provided risk information beyond the traditional scores, as EuroSCORE II and STS. Careful identification of risk factors and development of more suitable risk scores is essential.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Mortality, Renal failure, TAVR

TCT-625

The ECG after transcatheter aortic valve implantation determines the need for pacemaker implantation and the required duration of telemetry monitoring

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BACKGROUND Following transcatheter aortic valve Implantation (TAVI), patients are usually monitored by telemetry for a few days. However, there is currently no consensus on the duration of telemetry, and some patients may not require telemetry at all. In the present study, we sought to evaluate how the postprocedural ECG determines the need for pacemaker implantation and optimal duration of telemetry monitoring.

METHODS Patients without a permanent pacemaker undergoing TAVI at two centers in Switzerland were investigated. ECGs at baseline and post TAVI were analyzed to identify atrioventricular and interventricular conduction disorders. A normal ECG was defined as a QRS width $< 120 \text{ ms}$ and a PQ time $< 200 \text{ ms}$. The occurrence and timing of high degree atrioventricular block (AVB) and the need for Implantation of a permanent pacemaker was recorded.

RESULTS A total of 537 patients underwent TAVI with either the CoreValve ($n = 265$) or the SAPIEN XT or SAPIEN 3 ($n = 272$). None of the patients with a normal postprocedural ECG developed high degree atrioventricular block (AVB) or required implantation of a permanent pacemaker. Patients with a narrow QRS but impaired AV conduction required a pacemaker in 6/58 (9.4%), and heart block occurred as late as 3 days post procedure. Patients with a wide QRS and normal AV conduction required a pacemaker in 17/154 (11.0%) and heart block occurred up to 2 days post procedure. Patients with a wide QRS and impaired AV conduction required a pacemaker in 24/61 (39.3%) and heart block occurred as late as 5 days post procedure. Almost all patients (60/61, 98.4%) with a complete heart block post procedure required implantation of a permanent pacemaker.

CONCLUSIONS The postprocedural ECG was predictive of the required duration of telemetry monitoring regardless of the type of valve implanted. Patients with a normal ECG post TAVI did not develop high-degree heart block and did not require implantation of a permanent pacemaker. Such patients do not require telemetry and may be candidates for early discharge. Telemetry monitoring of 2 days should be considered for patients with wide QRS post TAVI. Patients with impaired AV conduction post TAVI required up to 5 days of telemetry monitoring. The findings of this study may help to improve in-hospital management of TAVI patients and reduce costs associated with this procedure.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, Transcatheter aortic valve implantation

TCT-626

Improvement in transcatheter aortic valve replacement outcome using the new generation SAPIEN 3 device: a single center experience

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BACKGROUND The SAPIEN 3 (Edwards Lifescience) balloon-expandable valve incorporates a paravalvular sealing system, an active 3-dimensional coaxial positioning catheter, and is compatible with a 14-F expandable sheath. These characteristics provide a theoretical superiority over previous device, including feasibility of TAVR (transcatheter aortic valve replacement) in a broader range of patients, better accuracy in valve positioning and less paravalvular regurgitation. We aimed to evaluate short-term outcomes in TAVR patients who benefited from 3rd generation SAPIEN 3 valve implantation and to compare these results to those obtained with the earlier generation SAPIEN XT device.

METHODS This single center prospective study included all patients who underwent TAVR with balloon-expandable SAPIEN valve